

PATENT
144002-2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: Douglas T. DIETERICH
 Serial No.: 09/862,404
 Filing Date: May 21, 2001
 For: **METHOD OF TREATING ANEMIA CAUSED BY RIBAVIRIN
TREATMENT OF HEPATITIS C USING ERYTHROPOIETIN ALPHA**
 Examiner: Canella, K.
 Art Unit: 1642

745 Fifth Avenue, New York, NY 10151
EXPEDITED PROCEDURE
RESPONSE AFTER FINAL
UNDER 37 C.F.R. 1.116

EXPRESS MAIL

Mailing Label Number: EV206802969US

Date of Deposit: April 7, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CHARLES JACKSON

(Typed or printed name of person mailing paper or fee)

Charles Jackson

(Signature of person mailing paper or fee)

DECLARATION

Mail Stop AF
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450
 Dear Sir:

PAUL KLOTHIAN, declares and states that:

1. I understand that I have been provided with a copy of the above application ("the present application") as published (Exhibit A), a copy of claims being advanced (Exhibit B), and a copy of Bruchfeld *et al.* ("Management of ribavirin treatment in renal insufficiency and dialysis," September 2000, Journal of the American Society of Nephrology, Vol. 11, Program and Abstract Issue, page 57) ("Bruchfeld") (Exhibit C). I have read and understand the documents of

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Exhibits A, B and C. A copy of my *Curriculum vitae* is attached as Exhibit D. I respectfully submit that I am considered by my peers to be a person skilled in the art to which the present application pertains, and am qualified to speak about the documents of Exhibits A, B and C, based upon my education, training, and experience, and that I have read and understand them.

2. In my opinion, Bruchfeld does not teach or suggest treating hepatitis C in an HIV-negative patient in need thereof comprising administering ribavirin (RBV) or RBV and interferon-alpha (IFN), wherein the improvement comprises administering Erythropoietin (EPO) concomitantly or sequentially or via co-administration with the RBV or with the RBV and IFN and the RBV is administered at a maximum effective dosage 800 to 1200 mg per day; and, would not direct the skilled artisan to such treatment. And, Bruchfeld, in my opinion, does not teach or suggest treating ribavirin or ribavirin and interferon-alpha induced anemia in hepatitis C patients comprising administering erythropoietin to a patient in need thereof as a liquid preparation subcutaneously, parenterally, intradermally, intramuscularly or intravenously wherein the ribavirin or ribavirin and interferon-alpha induced anemia is a result of treating said hepatitis C patients with a maximum ribavirin effective dosage of dosage 800 to 1200 mg per day; and, would not direct the skilled artisan to such treatment.

3. For instance, Bruchfeld does not teach or suggest employing doses of 800 to 1200 mg per day. Rather, Bruchfeld employed lower doses than 800 to 1200 mg per day. Moreover, Bruchfeld expressly teaches administering reduced dosages of RBV, in particular, administering 170 to 300 mg of RBV per day for dialysis patients and about 200 to 600 mg per day for kidney transplant patients. This is up to seven times less the amount of RBV than doses of 800 to 1200 mg per day. And I find the patient population in Bruchfeld to be comparable to HCV patients that are not on dialysis or did not have a kidney transplant because the patient population in Bruchfeld received iron as a supplement. Also, by expressly requiring and utilizing lower RBV dosages, Bruchfeld is constant with the state of the art (reduction of RBV dose to address anemia); and therefore, I find that Bruchfeld teaches away from employing RBV doses of 800 to 1200 mg per day. In this regard, I note that Bruchfeld expressly, "requires reduced ribavirin doses as well as close monitoring of ribavirin concentration" (emphasis added), contrary to employing RBV doses of 800 to 1200 mg per day.

4. Furthermore, Bruchfeld states that, "4/5 dialysis patients became HCV-RNA negative during treatment, but relapsed post-treatment," such that in my opinion, Bruchfeld is

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not teaching or suggesting any treatment of HCV or RBV or RBV+IFN-alpha anemia in HCV patients, since Bruchfeld teaches that her patients relapsed. In contrast, the present application and invention (Exhibits A, B) provide methods for actually treating HCV-infected patients. The present application and invention provides for administering RBV doses greater than 80% (10.6 mg/kg per day) [i.e., greater than 800 mg per day for a 165 pound patient] of the recommended dose, and hence provides a method for actually treating HCV-infected patients.

5. I further declare that all statements made herein, of my own knowledge, are true and that all statements made on information and belief are believed to be true and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4/7/2004

Paul Klotman
PAUL KLOTMAN
(print name)

CURRICULUM VITAE

August, 2003

Name Paul E. Klotman, M.D.
 Murray M. Rosenberg Professor of Medicine
 Chairman, Samuel Broadman Department of Medicine
 The Mt. Sinai Medical Center, New York

Mailing Address 387 West End Avenue
 New York, NY 10024

Telephone Number (W) 212-241-4200
Date of Birth July 26, 1950

Place of Birth Cleveland, Ohio

Social Security # 298-44-4006

Spouse:
 Mary Frances Earley Klotman
 Chief, Division of Infectious Diseases
 Irene and Dr. Arthur M. Fishberg Professor of Medicine
 Mount Sinai Medical Center, NY

Children
 Samuel Eric Klotman, Born April 14, 1989
 Alexander Isadore Klotman, Born November 15, 1990

Citizenship USA
Education
 B.S. 1972 University of Michigan, Ann Arbor, MI
 M.D. 1976 Indiana University Medical School, Indianapolis, IN

Postdoctoral Training
 1976-77 Intern, Dept. of Medicine, Duke University Medical Center
 1977-78 Jr. Asst. Res., Dept. of Medicine, Duke University Medical Center
 1978-79 Sr. Asst. Res., Dept. of Medicine, Duke University Medical Center
 1979-80 Research Fellow, Div Nephrology, Duke University Medical Center
 1980-81 Chief Medical Resident - Dr. James Wyngaarden Chair
 Duke University Medical Center
 1981-82 Research Fellow, Div Nephrology, Duke University Medical Center

Academic Appointments
 1980-1982 Associate in Medicine, Department of Medicine, Duke University Medical Center
 1982-1988 Assistant Professor of Medicine and Nephrology, Duke University Medical Center
 1988-1989 Associate Professor of Medicine and Nephrology, Duke University Medical Center
 1989-1993 Section Chief, Molecular Medicine, Laboratory of Developmental Biology/NIDR/NIH
 1993-1994 Tenured Intramural Section Chief, Viral Pathogenesis, Laboratory of Oral Medicine/NIDR/NIH
 1994-2001 Irene and Dr. Arthur M. Fishberg Professor of Medicine, The Mt. Sinai Medical Center, New York
 1997-2001 Vice Chairman for Research, Department of Medicine, The Mt. Sinai Medical Center, New York
 1998-Present Professor of Immunobiology, The Mt. Sinai Medical Center, New York
 1998-Present Professor of Gene Therapy, The Mt. Sinai Medical Center, New York

2001-Present The Mt. Sinai Medical Center, New York
 Murray Rosenberg Professor and
 Chairman, Samuel F. Bronfman Department of Medicine
 The Mt. Sinai School of Medicine, New York, NY

Hospital Appointments

| | |
|---------------------|---|
| 1976-89 | VA Staff Physician, Veterans Adm. Med. Center, Durham, NC (GS 13-5, 7/1/76 - 7/1/89) |
| 1976-93 | Staff Physician, Duke University Hospital, Durham, NC |
| 1980-82 | Duke Hospital Executive Committee, Durham, NC |
| 1980-82 | Pharmacy & Therapeutics Committee, Duke Hospital, Durham, NC |
| 1984-88 | Director, Duke University Hypertension Center, Durham, NC |
| 1995-Present | Chief, Division of Nephrology, Mt. Sinai Medical Center |
| 1995-Present | Attending Physician and Director Dialysis Services Mt. Sinai Medical Center |
| 2001-Present | Chief of the Medical Service, Mt. Sinai Medical Center, New York, NY |

Board Certification

| | |
|-------------|---|
| 1979 | Diplomat of the American Board of Internal Medicine #70820 |
| 1984 | Diplomat of the American Board of Internal Medicine Subspecialty - Nephrology #70820 |

Licensure

| | |
|------------------|-----------------------------|
| July 1995 | New York License # 199427-1 |
|------------------|-----------------------------|

Honors and Awards

| | |
|--|--|
| University of Michigan (1968-1972) | |
| 1972 | Phi Beta Kappa, University of Michigan |
| Indiana University Medical School (1972-1976) | |
| 1973 | Public Health Service Research Award |
| 1975 | Alpha Omega Alpha - Junior Year |
| 1976 | Academic Achievement Award, Indiana University |
| 1976 | Mosby Scholarship for Academic Achievement |
| 1976 | Upjohn Academic Achievement Award |
| 1976 | AMSA-UTMB Natnl. Student Research Award Am. Heart Assoc., |
| 1976 | Culpepper Foundation Research Award, Indiana Univ. Med. School |

Postgraduate (1976-Present)

| | |
|------------------------|--|
| 1977-79, 81, 86 | Recognized by Medical Student Body for Excellence in Teaching |
| 1983 | Housestaff Teacher Recognition Award |
| | Duke University Medical Center, Department of Medicine |
| 1988-89 | NIH Visiting Scientist |
| 1988 | Henry Christian Award for Medical Research-AFCR (Nephrology) |
| 1991 | Henry Christian Award for Medical Research-AFCR (Nephrology) |
| 1992 | Henry Christian Award for Medical Research-AFCR (Dermatology) |
| 1993 | Henry Christian Award for Medical Research-AFCR (Infect. Dis.) |
| 1993 | Elected to American Society of Clinical Investigation |
| 2001 | Elected to Association of American Physicians |

Professional Societies

| | |
|---------------------|---|
| 1982-Present | American Federation for Clinical Research |
| 1986-1989 | Councilor, Southern Section, AFCR |
| 1982-Present | American Society of Nephrology |
| 1982-Present | International Society of Nephrology |

| | |
|--------------|--|
| 1983-Present | American Physiological Society |
| 1987-1994 | Southern Society of Clinical Investigation |
| 1992-Present | American Society for Microbiology |
| 1993-Present | American Society of Biochemistry and Molecular Biology |
| 1993-Present | American Society of Clinical Investigation |
| 1996-Present | American Society for Virology |
| 1998-Present | American Society of Gene Therapy |
| 2001-Present | Association of American Physicians |
| 2001-Present | Association of Professors of Medicine |

Training Record

| <u>Trainee</u> | <u>Resident</u> | <u>Training Period</u> | <u>Dipl. Ed.</u> | <u>Sources of Support or Current Position</u> |
|--------------------|-----------------|------------------------|------------------|--|
| Confman, Thomas | Post | 7/83-6/85 | M.D. | Chief, Division of Nephrology, Duke University James Clapp Professor of Medicine & Nephrology Duke University Medical School |
| Barley, Mary | Post | 7/83-6/85 | M.D. | Chief, Division of Infectious Diseases, Mt. Sinai Medical Center Irene and Dr. Arthur M. Fishberg Professor of Medicine & Infectious Diseases |
| Smith, Stephen | Pre | 7/84-6/86 | M.D. | Associate Professor of Medicine & Hypertension Duke University Medical School |
| Svetkey, Laura | Post | 7/84-6/87 | M.D. | Director, Duke Hypertension Center Professor of Medicine & Nephrology, Duke University Medical School |
| Collins, Deirdre | Post | 7/86-6/88 | M.D. | Private Practice in Nephrology |
| Spurny, Robert | Post | 7/87-6/89 | M.D. | Associate Professor of Medicine, Duke University Medical School |
| Horikoshi, Satoshi | Post | 6/89-3/91 | M.D. | Asst. Chief of Nephrology, Juntendo University, Japan Professor of Medicine |
| Bruggeman, Leslie | Post | 1/89-7/91 | Ph.D. | Associate Professor of Medicine Case Western Reserve University |
| Ray, Patricio | Post | 1/90-12/93 | M.D. | Professor of Pediatrics, George Washington Univ. Med School |
| Kopp, Jeffrey | Post | 1/90-6/94 | M.D. | Intramural NIH Research Officer OS, PHS, NIDDK, NIH |
| Yang, Kamic | Pre | 6/92-6/93 | NA | University of Pennsylvania Medical student MSII |
| Adler, Scott | Pre | 7/91-7/93 | M.D. | Instructor, Department of Medicine, University of Pennsylvania, Philadelphia, PA |
| Rappaport, Jay | Post | 1/92-8/96 | Ph.D. | Professor of Neurovirology, Temple Medical School Associate Director of Molecular Virology Laboratory |

| | | | | |
|---|------|---------------------|---------------|---|
| Hans, Basil | Post | 7/93-6/95 | Ph.D. | Asst. Professor of Medicine & Physiology, Mt. Sinai Med. Center, NY |
| Greenwald, Daniel | Pre | 6/93-7/95 | M.D. | Chief Resident in Medicine, Stanford University |
| Teixeira, Avelino | Post | 7/95-Present | Ph.D. | Research Assistant Professor of Medicine Mt. Sinai Medical Center, NY |
| Cohn, Michael | Pre | 6/94-7/96 | M.D. | Resident in Medicine UCSF |
| Gharavi, Ali | Post | 6/96-6/97 | M.D. | Assistant Professor of Medicine, Columbia Physicians and Surgeons, NY |
| Ross, Michael J. | Post | 7/99-6/01 | M.D. | Asst. Professor of Medicine, Mt. Sinai Medical Center K08 |
| Ross, Michael D. | Pre | Ph.D. Awarded 10/02 | | MSTP Student, Mt. Sinai School of Medicine |
| Schwartz, Elissa | Pre | Ph.D. Awarded 6/02 | | Post Doc UCLA, Dr. Sally Blower |
| Marras, Danielle | Post | 7/00-6/02 | Ph.D. | Staff Scientist, Institute for Virologic Research, Genoa Italy |
| He, Cijiang | Post | 2000-2002 | M.D.,Ph.D. | Asst. Professor of Medicine Mt. Sinai School of Medicine K08 |
| <u>Current Post/Doc in the Laboratory</u> | | | | |
| Husain, Mohammad | Post | Current | Ph.D. | Supported NIH Grant Winner of the National Kidney Foundation Young Investigator Award (NYN) 2000 |
| Sunamoto, Masaaki | Post | Current | Visiting M.D. | Kyoto University Supported NIH Grant |
| Monahan, Marianne | Post | Current | M.D. | Supported by Renal Fellowship |
| Hayashi, Kayo | Post | Current | Visiting M.D. | Supported by a Grant from the Japanese Kidney Foundation |

Previous Grant Support

| Year | Amount/Yr. |
|-----------|-------------------|
| 1980-81 | \$20,000/year |
| | \$40,000 Total |
| 1980-86 | \$250,000/year |
| | \$1,000,000 Total |
| 1983-90 | \$120,000/year |
| | \$840,000 Total |
| 1986-89 | \$45,000/year |
| | \$135,000 Total |
| 1988-93 | \$650,000/year |
| | \$3,250,000 Total |
| 1988-94 | \$500,000/Year |
| 1996-97 | \$15,000/year |
| 7/97-6/99 | \$25,000 |
| 1996-2001 | \$1,000,000/yr |

Source

National Kidney Foundation Research Fellowship
Duke University Medical Center, Durham, NC
Consultant and Research Contracts
Pfizer, AH Robbins, American Cyanamide,
Hoffman LaRoche
Merit Review, Veteran's Administration (PI)
Renal Prostaglandin Metabolism
National Institute of Aging (CoPI)
CoPI: Hypertension in Elderly Blacks
NTH-PPG: PI: Pathophysiology of Renal
Allograft Dysfunction in the Rat - (PI)
Tenured Intramural Scientist
AMFAR: Growth failure in HIV transgenic mice
NKF fellow Cloning a 72kDa DNA channel (M. Sedlacek)
NIDDK: PPG Gene Therapy for Renal Disease

OTHER SUPPORT 2001

Paul Klotman, M.D.

Paul Klotman, M.D.

ACTIVE

5 T32 DK07757-03 (Klotman, Paul E.)

Source: National Institutes of Health NIDDK

Institutional National Research Service Award

Title: Molecular Basis of Renal Disease

7/1/98-6/30/03

\$84,695

0%

The objective of this project is to train talented young physician-scientists for a successful career in investigative nephrology.

1 P01 DK56492-04 (Klotman, Paul E.)

Source: National Institutes of Health/NIDDK

35% Total

Title: Pathogenesis of HIV-Associated Nephropathy

9/15/99-6/30/04

\$1,156,423

The major goals of this project are

1. To identify candidate genes methods that may be responsible for enhancing the severity of HIVAN or its phenotypic penetrance by position cloning.
2. To explore mechanisms of viral pathogenesis including the evolution of renal quasispecies, the mechanisms of viral entry, and the steps in the viral life cycle supported by the renal epithelia.
3. To explore viral-host interactions by determining which viral gene product(s) are responsible for initiating HIVAN and the host response to infection using representational difference analysis to identify candidate pathways.

1 R01 DK63610-01 (Klotman, Paul E.)

Source: National Institutes of Health/NIDDK

Title: Mechanisms of Nucleic acid Uptake by Renal Epithelium \$404,681 25% effort

06/20/2002 - 03/31/2006

The major goal of this project is to explore how strands of DNA enter cells. We have previously shown that single stranded DNA can move through a highly specific channel. We purified this protein complex and have been identifying what each component of this complex does. We have now identified one of the subunits of this channel as a common enzyme that serves also to regulate DNA uptake. The current proposal will evaluate other subunits and participant in this activity.

PENDING

None

Patents

1. Klotman PE, Bruggeman LA, and Horikoshi S. Method for quantifying laminin and beta actin mRNA. US Patent 07/929,204. Awarded November 26, 1993.
2. Rappaport J, Arya S, Klotman P. Use of HIV-2 as molecular therapy for HIV-1. Patent pending
3. Teixeira A, Klotman PE. Modified Anthrax delivery vehicles. Pending.
4. Hanss B and Klotman PE. Nucleic acid channels. Pending.
5. Gelman I and Klotman PI. Small molecules to inhibit Nef in the treatment of HIV complications. Pending

Visiting Professorships

- 1986 Division of Nephrology, Columbia University, New York, NY
 1989 Department of Medicine, University of Wisconsin Medical Center, Madison, WI
 1990 Division of Nephrology, Emory University, Atlanta, Georgia
 1990 Department of Medicine, Medical University of South Carolina, Charleston, SC
 1990 Department of Medicine & Division of Nephrology, Juntendo Univ., Tokyo, Japan
 1990 Johns Hopkins University School of Medicine, Baltimore, MD
 1990 University of California San Diego, La Jolla, CA
 1991 Div of Nephrology, Univ of Pennsylvania School of Medicine, Philadelphia, PA
 1991 Columbia University College of Physicians and Surgeons, New York, NY
 1992 Division of Nephrology, Montefiore and Albert Einstein Medical Centers
 1992 Dept. of Anatomy & Cell Biology, Medical Univ South Carolina, Charleston, SC
 1992 Dept. of Medicine and Div of Nephrology, Duke Univ Medical Center, Durham, NC
 1993 Department of Medicine and Division of Nephrology, Johns Hopkins, Baltimore, MD
 1993 Molecular Medicine Institute, Jefferson Medical College, Philadelphia, PA
 1996 Division of Nephrology, Dept. of Medicine, Columbia University, New York, NY
 1996 Department of Pathology, Yale University, New Haven, CT
 1996 Division of Nephrology, Duke University Medical Center, Durham, NC
 1997 Department of Medicine, New York University Medical Center, New York, NY
 1997 Department of Medicine, New York Medical College, Valhalla, NY
 1998 Division of Nephrology, Duke University Medical Center, Durham, NC
 1999 UCLA Max Martin Salick Visiting Professor, Torrance, CA
 4/00 Division of Nephrology, UT Southwestern Medical Center, Dallas, TX
 5/00 Division of Nephrology, Indiana University Medical School, Indianapolis, IN
 8/00 Division of Nephrology, Duke University, Durham NC
 11/01 Department of Medicine, UC San Diego, San Diego CA
 1/02 Division of Nephrology, University of Colorado, Denver CO
 2/02 Department of Medicine, Northwestern University, Chicago IL
 3/02 Department of Medicine, Albert Einstein College of Medicine, Bronx, NY
 1/03 Ike Robinson Visiting Professorship, Duke University Medical Center, Durham, NC
 9/03 NKF Saulo Klahr Lecture, Washington University School of Medicine, St. Louis, MO
 1/04 CFAR Lecturer, Department of Medicine, Vanderbilt University, Nashville TN

Invited Lectures at National and International Meetings and Symposia

- 1986 Southeastern Organ Procurement Foundation, Tampa, FL
 "Role of Thromboxane in Renal Allograft Rejection"
 1986 Alexis Carrel Symposium, Georgetown Med Cntr, Washington, DC
 "Lipid Mediators in Renal Allograft Rejection"
 1986 National Kidney Foundation, Charlotte NC
 "Prostaglandins in Diabetic Renal Disease"
 1987 American Society of Nephrology, Washington, DC
 "Thromboxane Receptors and Inhibitors"
 1988 International Symposium on the Prevention, Treatment & Diagnosis of Acute Renal Failure, Edmonton, Alberta, Canada, "Thromboxane and Renal Dysfunction"
 1989 American Society of Nephrology, Washington, DC
 "Molecular Mechanisms of Cyclosporin Toxicity"

- 1990 NIH Research Symposium
Workshop on Polypeptide Mediators of Inflammation & Repair, Bethesda, MD
"Role of Eicosanoids in Extracellular Matrix Gene Expression"
- 1991 NIH Highlights from the NIDR
"HIV Associated Nephropathy in Transgenic Mice"
- 1991 Int'l. Conf on the Molecular bases of Hepatic Cirrhosis, INSERM, Rennes, France.
"Progressive renal failure: role of extracellular matrix proteins"
- 1992 National Institute of Aging, Baltimore, MD
"Transgenic Models of Viral Disease"
- 1992 Laboratory of Tumor Cell Biology Annual Meeting, Bethesda, MD
"Transgenic Mice as Models for HIV Pathogenesis and Therapy"
- 1993 Sixth Int. Symposium on Basement Membrane, Fuji Conference Cntr, Shizukoka, Japan
"Potential roles for bFGF and TGF- β in the pathogenesis of AIDS-associated nephropathy in transgenic mice"
- 1993 American Society of Nephrology, Boston, MA
"Gene Therapy Symposium"
- 1993 New York Society of Nephrology, New York, NY
"Pathogenesis of HIV Associated Nephropathy"
- 1994 American Society of Nephrology, Orlando, FL
"Molecular Biology Symposium: Advances in Gene Therapy"
- 1994 American Society of Nephrology, Orlando, FL
"HIV-1 and the Kidney"
- 1996 Harvard Medical School CME Course, Beth Israel, Boston, MA
"HIV Associated Nephropathy"
- 1996 Harvard Medical School CME Course, Brigham and Women's Hospital, Boston, MA
"New Insights into HIV Associated Nephropathy"
- 1997 Harvard Medical School CME Course, Brigham and Women's Hospital, Boston, MA
"Pathogenesis of HIV associated nephropathy"
"Gene Therapy"
- 1997 Japanese Society of Nephrology, Niigata, Japan
"Transgenic Models of Renal Disease"
- 1997 International Congress of Nephrology, Sydney Australia
"Transgenic Models of Renal Disease"
- 1997 Harvard Medical School CME Course, Beth Israel, Boston, MA
"Clinical Update: HIV associated nephropathy"
- 1997 American Society of Nephrology, San Antonio Texas
Symposium Director: Clinical Issues in HIV Associated Nephropathy
"Advances in HIV Pathogenesis and Therapy"
- 1998 Harvard Medical School Symposium: From Bench To Bedside
Brigham and Women's Hospital, Boston, MA
"Updates in HIV associated nephropathy"
"Molecular Therapy"
- 1998 Harvard Medical School CME Course, Beth Israel, Boston, MA
"Clinical Update: HIV associated nephropathy"
- 1998 ACTG Investigators Meeting, San Francisco, CA
"Nucleotide analog-induced Fanconi Syndrome"
- 1998 International AIDS Society, New York NY
"Renal Complications in HIV Disease"
- 1998 Scientific Session of the Consortium for Southeastern Hypertension Control
"Genetic factors that influence the development of HIVAN in African Americans"
- 1998 World Health Communications: Comprehensive Management of HIV Disease
"Novel HIV therapeutics: Adesovir"
- 1998 Molecular Biology Course: ASN
"Gene Therapy"
- 1998 Columbia University Pathology CME Course
"Clinical and Pathological Features of HIV associated nephropathy"

- 1999 Harvard Medical School CME Course, Beth Israel, Boston, MA
 "HIV associated nephropathy".
- 1999 German Society of Nephrology
 State of the Art Lecture: "AIDS and the Kidney"
- 1999 Columbia University Pathology CME Course
 "Clinical and Pathological Features of HIV associated nephropathy"
- 6/1/00 Organizer: International Society of Nephrology
 Frontiers in Nephrology: Gene Therapy
- 8/19/00 Int'l. Society of Hypertension: End Stage Renal Disease – Genetics to Therapy
 "Gene Therapy in Kidney Disease"
- 3/19/02 Optimal Management of HIV Disease: Clinical Conference
 Management of renal disease in HIV-1 patients
- 9/26/02 HIV Nephropathy
 Post Graduate Medical Conference, Columbia University College of Phys & Surgeons
- 12/3/02 Adefovir Management
 Japanese Regulatory Agency for Drug Development
- 11/14/03 "Has HAART altered the course of HIVAN?"
 Virus-associated Glomerulopathies Symposium
 American Society of Nephrology, San Diego, 2003
- 12/4/03 Animal Models for HIV associated nephropathy
 Workshop on Animal Models for Studying HIV Pathogenesis
 Center for Neurovirology and Cancer Biology, Temple University, Medical Center

Editorial Boards

- 1991-95 American Journal of Physiology
- 1993-Present Seminar in Nephrology
- 1998-July Guest Editor, Seminars in Nephrology HIV and the Kidney
- 1994-2001 Journal of Molecular Medicine
- 1995-1999 Associate Editor, Journal of Molecular Medicine
- 1996-2001 Journal of the American Society of Nephrology
- 1997-2002 Associate Editor, American Journal of Kidney Disease
- 2001-Present American Journal of Physiology, Renal

Academic Advisory Committees

- 1984 Pew Research Awards Committee
- 1986 First Annual Alexis Carrel Conference Lipid mediators in Organ Transplantation: International Advisory Committee
- 1993 Sixth International Symposium on Basement Membrane: International Advisory Committee
- 1994 Seventh International Symposium on Basement Membranes: International Advisory Committee

Industry Advisory Committees

- 1998-Present Gilead Scientific Advisory Board
- 1998-Present Genzyme Ad Hoc Consultant
- 1999-Present Ariad Ad Hoc Consultant
- 2000-Present Coordinated Care Solutions Advisory Board
- 2000-Present Fibrogen Ad Hoc Consultant
- 2001-Present ANDRX Ad Hoc Consultant

American Heart Association

- 1990-1993 American Heart Association: Renal Study Section

Veteran's Administration

- 1985 Veteran's Administration: Career Development Study Section
- 1988, 1990-93 Nephrology Merit Review Board Study Section
- 1992-1993 Chairman, Nephrology Merit Review Board Study Section

American Federation for Medical Research

- 1984 AFCR Program Selection Committee

1986 AFCR Program Selection Committee
 1987 AFCR Program Selection Committee
 1982-85 AFCR Councillor: Southern Section Representative
National Institutes of Health
 1984 NIH/NHLBI: Study Section: Systolic Hypertension in the Elderly
 1988-1990 NIH/NIDDK: Kidney Disease of Diabetes Mellitus
 1989-1994 NIH: HIV Task Force Committee
 1989-1994 NIH: Urologic and Renal Disease Committee
 1989-1994 NIH/NIDR: Clinical Studies Committee
 1989-1993 NIH/NIDR: Member Visiting Scholars Committee
 1990-1994 NIH/NIDR: Chairman Visiting Scholars Committee
 1993-1994 NIH/NIDR: Human Use Committee
 1993-1994 NIH/NIAID: Advisory Member to the Office of AIDS Research
 1993-1994 NIH/NCRR: Central Facilities Advisory Committee for the Veterinary Resources Program
 1994-1996 NIH/OAR: Member Office of AIDS Research Planning Committee
 1993-1994 NIH/NIAID: Study Section: National Cooperative Drug Discovery Groups for the Treatment of Human Immunodeficiency Virus Infection
 1998 NIAID: Study Section: HIV Pathogenesis ad hoc
 1999 NCI: Study Section: Oligonucleotide chemistry and therapy ad hoc
 1999 NIDDK: Study Section: Center Grants for Polycystic Kidney Disease

American and International Societies of Nephrology
 1984 IXth Int. Congress of Nephrology, Program Committee
 1984-86 Am. Soc. of Nephrology, Program Committee,
 1990 Am. Soc. of Nephrology, Section Chairman & Program Committee
 1993 Am. Soc. of Nephrology, Symposium Chairman: Gene Therapy
 1994 Am. Soc. of Nephrology, Program Committee
 1997-2002 Chairman, Homer Smith Award Committee
 American Society of Nephrology
 1999 American Society of Nephrology Program Committee
 2000 International Society of Nephrology:
 2001 Frontiers in Nephrology "Gene Therapy" (Meeting Organizer)
 2002 Program Committee, ASN/ISN
 Program Committee Chairman, ASN

National Kidney Foundation
 1990 Michigan Kidney Foundation Grant Awards Committee
 1991-1995 National Kidney Foundation, Fellowship Rev. Committee
 1995-Present NY/NJ National Kidney Foundation Award Review Committee
 1999-2001 Chairman, NKF Fellowship Review Committee (National)
 1999-2001 Chairman, NKF Scientific Advisory Committee (National)

Mt. Sinai Committees
 1993-Present Research Residency Program Committee, Mt. Sinai Medical Center
 1993-Present Housestaff Advisory Committee, Mt. Sinai Department of Medicine
 1993-Present Committee for Institutional Research Expansion
 1996-Present Director Research Residency Program, Mt. Sinai School of Medicine
 1999-Present Chairman, Ethical Conduct Committee, Mt. Sinai School of Medicine
 1999-Present Appointments and Promotions Committee, Dept. of Medicine Mt. Sinai
 1998-Present Housestaff Advisory Committee, Dept. of Medicine, Mt. Sinai
 1998-Present Housestaff Selection Committee, Dept. of Medicine, Mt. Sinai
 1999-Present Research Strategic Planning Committee, Mt. Sinai School of Medicine
 1999-Present Patient Oriented Research Committee, Mt. Sinai School of Medicine
 2000-Present Faculty Practice Executive Committee
 2000-2001 Hunter Steering Committee

2000-2001
2003-Present
2003-Present

CEO and Dean Search Committees
Vice President, Faculty Practice
Chairman, Institutional Strategic Planning Committee

PUBLICATIONS

Original Peer-Reviewed Reports

1. Klotman PE, Grim CE, Weinberger MH, Judson WE. The effects of Minoxidil on pulmonary and systemic hemodynamics in hypertensive man. *Circulation* 55: 894, 1977.
2. Grim CE, Luft FC, Grim CM, Klotman PE, Van Huyse JW, Weinberger MH. Rapid blood pressure control with Minoxidil. *Archives of Internal Medicine* 139: 529, 1979.
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